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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/495,186 | 02/01/2000 | John McMichael | 13024/35946 | 4501 |

7590 04/10/2007

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| EXAMINER | |
|---|---|
| WILSON, MICHAEL C | |
| ART UNIT | PAPER NUMBER |
| 1632 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 04/10/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/495,186 | MCMICHAEL ET AL. | |
| | Examiner | Art Unit | |
| | Michael C. Wilson | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *3-8-04 & 3-11-04 & 6-17-04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-11-04 has been entered.

Applicant's arguments filed 3-11-04 and 3-8-04 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The examiner's amendment filed 12-1-01 has been entered. Claims 15-19 are pending and under consideration.

The petition to revive was granted on 10-26-04. Prosecution on the merits has been reopened.

### *Claim Rejections - 35 USC § 112*

Claims 15-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Claim 15 requires treating a patient having pain caused by otitis media comprising the steps of: administering eardrops to the ear of said patient in a manner so as not to effect gene transfer, thereby reducing said pain, wherein said eardrop comprises an effective amount of DNA in a pharmaceutically-acceptable vehicle.

Otitis media is caused by bacteria or viruses in the ear and results in tympanic membrane retraction, bulging, redness and immobilization (Klein of record, 1994, Clinical Infectious Disease, Vol. 19, pg 823-833). Treatment with analgesic and decongestants do not alter the course of the infection, as neither have an effect on the bacteria or virus causing the disease. Thus, the person of skill in the art would conclude that the only management methods for treating otitis media itself, and not just symptoms of otitis media, are those that result in the reduction of bacteria or virus numbers. The prior art taught that even administering placebo to patients having otitis media results in decreasing the number of bacteria. Dagen of record (1988, Ear, Nose and Throat J., Vol. 77, pg 16-19) taught administering placebo to patients with otitis media caused by *H. influenza* resulted in a decrease in 48% of the bacteria present. Administering placebo to patients with otitis media caused by *S. pneumococcus* resulted in a decrease in 16% of the bacteria present. Examples XX, XXI, XXIV and XXV are directed to the treatment of pain; however, the specification does not evidence in these examples, or elsewhere in the disclosure the reduction in the number of bacteria or virus which cause otitis media. Nor do the examples have controls that teach obtaining results better than a placebo effect. Thus, applicants have not provided evidence of patients receiving treatment results in the decrease in the number of bacteria or virus or that the results

obtained are greater than a placebo effect. Furthermore, it is reasonable to assume that the ear of an individual already has DNA in the fluid within the ear as viral and bacterial particles contain DNA. However, the specification does not provide adequate guidance indicating that the minute amount of DNA being added in the eardrop is effecting a change in the symptoms or the amount of pathogen in the ear. Therefore, it would require one of skill undue experimentation to obtain a therapeutic effect against otitis media that is a direct result of administering eardrops containing DNA.

Applicants argue the reduction of bacteria does not necessarily correlate with otitis media and that the treatment of infection is not necessarily sufficient to treat the symptoms of otitis media. Applicant's argument is not persuasive. Applicants provide a definition that states otitis media is caused by viral or bacterial infection and results in inflammation. The definition provided does not state inflammation is not relieved upon elimination of infection. It cannot be determined how applicants have come to such a conclusion. Applicants have not provided any reference that states inflammation persists in the absence of virus or bacteria. The presence of bacteria/virus does correlate with otitis media and the reduction in virus or bacteria does cause a decrease in inflammation (Dagan of record, pg 16, Introduction; pg 17, "Causative organisms").

Applicants argue the method claims is not antibacterial. Applicants' argument is not persuasive. The claims encompass treating otitis media caused by bacterial infections, especially in view of the definition of otitis media provided by applicants that states otitis media is caused by viral or bacterial infection and results in inflammation. Overall, the specification does not provide evidence that the method claimed reduces

the number of bacteria or virus or provide any controls indicating the method claimed provides anything more than a placebo effect.

Applicants argue recent news reports suggest not treating otitis media with antibiotics. The news report in 2004 (Groups Urge No Antibiotics for Earaches) was not available at the time of filing. Furthermore, the claims encompass treating otitis media caused by bacterial infections. Finally, the specification does not provide evidence that the method claimed reduces the virus load or provide any controls indicating the method claimed provides anything more than a placebo effect.

Applicants argue otitis media can be categorized as acute or serous. Applicants' arguments are not persuasive. The claims encompass treating otitis media caused by bacteria (acute). Furthermore, the specification does not provide evidence that the method claimed reduces the viral load or provide adequate controls indicating the method claimed provides anything more than a placebo effect. Without such guidance, the specification does not enable one of skill to use the method claimed as a treatment.

Applicants argue applicants have demonstrated the successful use of the method claimed in both acute and serous otitis media. Applicants suggest the mode of action of the method claimed might be anti-inflammatory or relate to clearance of fluid. Applicants' argument is not persuasive. The specification does not provide evidence that the method claimed causes a therapeutic effect by providing adequate controls. Those of skill in the art of medical research would have clearly recognized that without comparison to placebo and in view of the known placebo effect found in otitis media supported by DAGEN, the anti-inflammatory effect observed may be a placebo effect

and that the product administered may not affect the inflammatory response. Applicants have provided no evidence that the anti-inflammatory response observed was anything more than a placebo effect.

The rejection of claims 15-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn because the phrase was allowed in parent cases.

***Conclusion***

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER